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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,079	01/18/2006	Jun Keun Chang	CHANG216	3911
1444 7590 05/26/2009 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER KINGAN, TIMOTHY G	
			ART UNIT 1797	PAPER NUMBER
			MAIL DATE 05/26/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,079	Applicant(s) CHANG ET AL.	
	Examiner TIMOTHY G. KINGAN	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 03/09/2009 have been fully considered but they are not persuasive. The invention of Hillman comprises a device suitable for biological or biomedical applications, including particle counting, as acknowledged by applicant. Suggestion for using Hillman's device in red blood cell counting is provided in the background section. While applicant correctly states that fluid flows in the device of Hillman by capillary action, Hillman does not claim or require detection of particles in the flowing state. Further, the method of use of Hillman's device is not pertinent to applicant's device claim. Intended use language in apparatus claims is not accorded patentable weight where the statement of intended use does not distinguish over the prior art apparatus (MPEP 2111.02). Here, Hillman teaches elements of applicant's invention, including upper and lower substrates forming fill chambers for fine particles (Fig. 2A, **60**). Other elements of the claim are taught by Risch, a second device for counting fine particles, and the technical or logical motivation for their incorporation in the device of Hillman would be obvious to one of ordinary skill in the art of hematology and use of hemocytometers, that being the capability that grids provide for quantitative determination of particle number or number per unit volume of sample. While Hillman does not specifically teach transparent upper and lower substrates defining chambers and channels, use of such property with the substrates would have been obvious to one of ordinary skill in the art from the teaching of Hillman on photodetection comprising

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light sources and light detectors. Particle counters require light sources for illuminating a counting or detection chamber, typically from below, and a means of viewing the chamber, typically from above and often through a microscope or other suitable photodetector, such features requiring (optically) transparent substrates.

Examiner notes that making the method claims dependent on the device claim does not in itself mean that the inventions are not distinct. In view of this consideration, as well as those in the rejection below, the restriction requirement is proper and is maintained.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over R.S. Hillman et al., U.S. Patent 4,963,498 (herein after Hillman) in view of O. Risch, U.S. Patent 1,693,961 (herein after Risch).

For Claim 1, Hillman teaches a microfluidic device suitable for particle counting (col 1, lines 28-37) comprising a three-layered device with three chambers, including a receiving chamber (fill chamber of predetermined height) and an inlet port (col 19, lines 38-49) (injecting hole for sample containing particles). Hillman does not teach a fine lattice pattern on the lower substrate. Such lattice or grid patterns are known in the art

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of devices for visual inspection and counting of cells or particles in liquid samples; Risch teaches a hemocytometer for counting blood cells, the glass body of which is provided with rulings or gratings (p. 1, ¶ 4; Fig. 1). It would have been obvious to one of ordinary skill in the art to include the gratings (lattice) of Risch on the lower substrate in the metering and inspection device of Hillman in order to provide the well known advantage of such gratings for counting cells or particles by manual or automated optical inspection.

Hillman does not specifically teach an area of the fill chamber in the upper and lower substrates being transparent for a microscopic observation. However, Hillman teaches use of physiological fluids such as blood (col 4, lines 17-20) and the capability of the device for counting of particles (col 20, lines 14-17). Further, Hillman teaches capabilities for photodetection comprising light sources and light detectors in scattering measurements (col 24, lines 13-25). It would have been obvious to one of ordinary skill in the art from such related teachings to use the property of transparency of the substrates, in order to provide for use of light sources for illuminating a counting chamber, typically from below, and a means of viewing the chamber, typically from above and often through a microscope, such features requiring (optically) transparent substrates.

For Claim 2, Hillman teaches exit and intermediate vents in communication with the receiving chamber (fill chamber) (col 19, lines 62-64) (for discharging sample or an air bubble).

For Claims 3-4, Hillman teaches bonding of the layers of the device with use of ultrasonic welding or solvent bonding (col 15, lines 8-11) (to form an integrated device).

For Claim 5, Hillman teaches a device in the region of the fill chamber comprising 2 mils or greater in height (ca. 58 microns) (col 15, lines 50-52), within the dimension of the instant claim.

For Claim 7, Hillman and Risch do not teach an indicative member on the upper substrate. It would have been obvious to one of ordinary skill in the art to place an indicative member on the upper substrate in order to facilitate coarse positioning of the counting chamber, and the lattice therein, the fine markings of which may otherwise be difficult to locate in a method of counting involving microscopy.

For Claim 8, Hillman teaches the layers (upper and lower substrates) of the device comprise plastic, suitable plastics including polycarbonate and polyethyleneterephthalate (col 14, lines 42-57) (upper and lower surface is made of plastic).

For Claim 9, Hillman teaches devices suitable for use in with red-blood-cells (col 1, lines 35-37; col 17, lines 41-48).

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY G. KINGAN whose telephone number is (571)270-3720. The examiner can normally be reached on Monday-Friday, 8:30 A.M. to 5:00 P.M., E.S.T..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TGK

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797